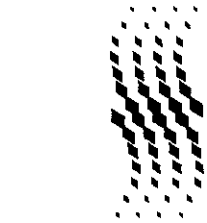

NOV 2 1 2007

510(k) Summary

510(k) Number: K072618

Date Prepared
September 14, 2007

Submitter Information

Submitter's Name/ Address:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369
Establishment Registration	2134812
Contact Person:	Alyssa Malinski amalinski@vascularsolutions.com

Device Information

Trade Name: Twin-Pass™ OTW Dual Access Catheter
Common Name: Percutaneous Catheter
Classification Name: Unclassified
Product Code: DQY
Regulation: 21 CFR 870.1250

Predicate Device(s)
Twin-Pass™ Dual Access Catheter (K052257)
Twin-Pass™ Dual Access Catheter (K060327)

Device Description
The Vascular Solutions Twin-Pass OTW Catheter is a sterile single use device designed for use in the arterial vasculature. The catheter provides support for 0.014"/0.36mm guidewires during interventional procedures, and the dual lumen design allows for the

delivery of a second guidewire, contrast, or medication into distal vasculature while leaving the initial guidewire in place.

Intended Use/Indications for Use
The Twin-Pass OTW Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Summary of Non-Clinical Testing
Testing conducted included assessments of the design verification of the Twin-Pass OTW Catheter along with biocompatibility assessments. Shelf life testing was leveraged from the Twin Pass Dual Access Catheter (K052257 and K060327). The results of this testing confirmed the suitability of the Twin-Pass OTW Catheter for its intended use. Each bench test that was conducted is listed, below:

- Tortuosity
- Catheter Kink Resistance
- Radiopaque Markerband
- Hub-to-proximal-shaft Bond Strength
- Proximal-to-distal-shaft Bond Strength
- Fluid Leak Under Pressure
- Air Leak During Aspiration
- Flow Rate (Infuse and Distal Lumen)
- Infuse Lumen Flow Rate
- Guidewire Interface
- Guide Catheter Interface

Summary of Clinical Testing
No Clinical Testing was conducted for Twin-Pass™ OTW Catheter.

Statement of Equivalence
The Twin-Pass OTW Catheter is considered to be substantially equivalent to the Twin-Pass Dual Access Catheter (K052257 and K060327). The indications for use selected for the Twin-Pass OTW Catheter are a combination of the indications for use of the predicates. In addition, the products are covered by the same regulation, are made of same materials, have similar sizes and have similar features.

Conclusion
The data submitted in the following sections demonstrates that the Twin-Pass OTW Catheter is a safe and effective means delivering supporting steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Vascular Solutions, Inc.
c/o Ms. Alyssa Malinski
Regulatory Affairs Assistant
6464 Sycamore Court
Minneapolis, MN 55369

Re: K072618
Trade/Device Name: Twin-Pass™ OTW Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 15, 2007
Received: November 16, 2007

Dear Ms. Malinski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072618

Device Name: Twin-Pass™ OTW Catheter

Indications for Use:
The TwinPass OTW Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Prescription Use X		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072618